January 27, 2003

David Martinez
TWCC Medical Dispute Resolution
4000 IH 35 South, MS 48
Austin, TX 78704

MDR Tracking #: M2-03-0506-01
IRO #: 5251

___ has been certified by the Texas Department of Insurance as an Independent Review Organization. The Texas Worker's Compensation Commission has assigned this case to ___ for independent review in accordance with TWCC Rule 133.308 which allows for medical dispute resolution by an IRO.

___ has performed an independent review of the proposed care to determine if the adverse determination was appropriate. In performing this review, all relevant medical records and documentation utilized to make the adverse determination, along with any documentation and written information submitted, was reviewed.

The independent review was performed by a matched peer with the treating doctor. This case was reviewed by a licensed Medical Doctor with a specialty and board certification in Physical Medicine and Rehabilitation. The ___ health care professional has signed a certification statement stating that no known conflicts of interest exist between the reviewer and any of the treating doctors or providers or any of the doctors or providers who reviewed the case for a determination prior to the referral to ___ for independent review. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

CLINICAL HISTORY

___ is a 51-year-old female dietary aid who injured her low back when she picked up a 50 pound box of apples. She saw ___ on 2/6/00 and was treated for a bladder infection. On follow-up, she had a lumbar spine x-ray that was reported as normal and was treated with a muscle relaxant. She had several IM steroid injections that did not provide relief. She had a lumbar MRI that identified diffuse annular disc bulge at L4/5 impinging on the thecal sac. She had one lumbar ESI by ___ and two additional ESIs by ___ without relief. She participated in PT three times per week without relief. She had an EMG by ___ that was reported as normal. She was seen by ___ for a surgical opinion. She was seen by ___ for pain management. ___ proposed treating ___ with an Orthofix device, a device which decreases pain in the back by off-loading pain-sensitive structures like discs. ___ responded with non-authorization due to a lack of non-proprietary research that would support the efficacy of the Orthofix device. Orthofix Inc. appealed by pointing out that the device is a non-powered orthopedic traction apparatus and is exempt from pre-market notification procedures in subpart E of part 807 of the Federal Regulation Code. ___

responded by a peer review form ___ who opined that no further treatment was necessary for this patient. Then ___ had ___ provide an opinion that he agreed with earlier doctors that there was no literature to support the effectiveness of the Orthofix device. ___ states that he even had representative of the device in his office four months earlier demonstrating how the device worked. He proposed that the patient be allowed to try the Orthofix device for eight weeks. If the device offered no objective benefit, the accepted cost of the device would be the manufacturer's cost of $500. If the device demonstrated objective improvement after eight weeks, Orthofix would be entitled to the full cost of the device, $1750. The manufacturer introduced a Limited Risk Sharing Program proposing that the device would be manufactured, delivered and a patient in-service would be done for $500. If in 30 days the patient has had relief of pain and wants to continue to use the device, the device cost would increase to $1750, less co-pay and deductibles.

REQUESTED SERVICE

The purchase of an Orthotrac Pneumatic Vest is requested for ___.

DECISION

The reviewer agrees with the prior adverse determination.

BASIS FOR THE DECISION

The manufacturer and treating doctor have not provided supporting evidence that allows determining the medical necessity of the Orthofix device. The company and the treating doctor have proposed the use of the Orthofix device as a means to allow the claimant to be able to function and not be hampered with low back pain. From the documentation provided, there was no supporting documentation indicating that the claimant had relief by laying down and/or documentation that other lumbar spine off-loading techniques have been used to increase the function of this patient (aqua-therapy, off-loading therapy devices with therapy notes to substantiate the need). The reviewer is familiar with this device through his own research. Fitting is important if it is to work at all. The device is bulky and can be uncomfortable to wear for the hours needed to be effective. A trial of use is needed to determine if an individual will be able to benefit from the device. Forte provided a strong argument against the Orthofix device, but the treating doctor and the Orthofix company failed to provide clinical information that would have helped this patient to have the benefit of this device.

___ has performed an independent review solely to determine the medical necessity of the health services that are the subject of the review. ___ has made no determinations regarding benefits available under the injured employee's policy.

As an officer of ___, I certify that there is no known conflict between the reviewer, ___ and/or any officer/employee of the IRO with any person or entity that is a party to the dispute.

___ is forwarding by mail and, in the case of time sensitive matters by facsimile, a copy of this finding to the treating doctor, payor and/or URA, patient and the TWCC.

Sincerely,

YOUR RIGHT TO REQUEST A HEARING

Either party to this medical dispute may disagree with all or part of the decision and has a right to request a hearing.

In the case of prospective ***spinal surgery*** decision, a request for a hearing must be made in writing and it must be received by the TWCC Chief Clerk of Proceedings within 10 days of your receipt of this decision. (20 Tex. Admin. Code 142.5(c)).

In the case of other ***prospective (preauthorization) medical necessity*** disputes a request for a hearing must be in writing, and it must be received by the TWCC Chief Clerk of Proceedings within **20** (twenty) days of your receipt of this decision (28 Tex. Admin. Code 148.3).

This decision is deemed received by you 5 (five) days after it was mailed (28 Tex. Admin. Code 102.4(h) or 102.5(d). A request for a hearing should be sent to: Chief Clerk of Proceedings, Texas Worker's Compensation Commission, P.O. Box 40669, Austin, TX 78704-0012. A copy of this decision should be attached to the request.

The party appealing this decision shall deliver a copy of its written request for a hearing to all other parties involved in the dispute, per TWCC rule 133.308(t)(2).